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PATENT
Attorney Docket No. LEX-011

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Gillies *et al.* CONF. NO.: 8264
SERIAL NO.: 09/780,668 GROUP NO.: 1644
FILING DATE: February 9, 2001 EXAMINER: David A. Saunders
TITLE: ENHANCING THE CIRCULATING HALF-LIFE OF
ANTIBODY-BASED FUSION PROTEINS

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**

- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**
- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

Date: September 28, 2004
Reg. No. 48,645

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Respectfully submitted,



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FORM PTO - 1449

THIRD SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT

ATTORNEY DOCKET NO.: LEX-011

APPLICANT(S): Gillies *et al.*

SERIAL NO.: 09/780,668

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U.S. PATENT DOCUMENTS

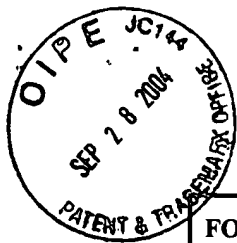
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A97	5,601,819	2/11/97	Wong et al.			
	A98	5,891,680	4/6/99	Lieschke et al.			
	A99	5,994,104	11/30/99	Anderson et al.			
	A100	6,429,199	8/6/02	Krieg et al.			
	A101	6,500,641	12/31/02	Chen et al.			
	A102	6,551,592	4/22/03	Lindhofer et al.			
	A103	6,646,113	11/11/03	Dreyfuss et al.			
	A104	2002/0037558	3/28/02	Lo et al.			
	A105	2002/0146388	10/10/02	Gillies			
	A106	2003/0139365	7/24/03	Lo et al.			
	A107	2003/0139575	7/24/03	Gillies			
	A108	2004/0013640	1/22/04	Zardi et al.			
	A109	2004/0033210	2/19/04	Gillies			
	A110	2004/0043457	3/4/04	Schumacher et al.			
	A111	2004/0053366	3/18/04	Lo et al.			
	A112	2004/0072299	4/15/04	Gillies et al.			
	A113	2004/0082039	4/29/04	Gillies et al.			

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNT RY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B107	WO 93/20185	10/14/93	PCT					

EXAMINER

DATE CONSIDERED



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		FILING DATE: February 9, 2001 GROUP: 1644	
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)		
	C241	Chapman et al., (1994), "Mapping Effector Functions of a Monoclonal Antibody to GD3 by Characterization of a Mouse-Human Chimeric Antibody," <u>Cancer Immuno. Immunother.</u> , 39:198-204.	
	C242	Conner et al., (2004), "Ex vivo Evaluation of Anti-EpCAM Immunocytokine huKS-IL2 in Ovarian Cancer," <u>J. Immunotherapy</u> , 27:211-219.	
	C243	de la Salle et al., (1996), "FcγR on Human Dendritic Cells," in <u>Human IgG Receptors</u> , pp. 39-55, van de Winkel et al. (eds.), R.G. Landes Co.	
	C244	Dorai et al., (1991), "Aglycosylated Chimeric Mouse/Human IgG1 Antibody Retains Some Effector Function," <u>Hybridoma</u> , 10(2):211-217.	
	C245	Dorai et al., (1992), "Role of Inter-Heavy and Light Chain Disulfide Bonds in the Effector Functions of Human IgG1," <u>Molecular Immunology</u> , 29(12):1487-1491.	
	C246	Elliott et al., (1996), "Fine-Structure Epitope Mapping of Antierythropoietin Monoclonal Antibodies Reveals a Model of Recombinant Human Erythropoietin Structure," <u>Blood</u> , 87(7):2702-2713.	
	C247	Gillies et al., (1991), "Targeting Human Cytotoxic T Lymphocytes to Kill Heterologous Epidermal Growth Factor Receptor-Bearing Tumor Cells: Tumor-Infiltrating Lymphocyte/Hormone Receptor/Recombinant Antibody," <u>J. Immunology</u> , 146(3):1067-1071.	
	C248	Handgretinger et al., (1995), "A Phase I Study of Human/Mouse Chimeric Anti-ganglioside GD2 Antibody ch14.18 in Patients with Neuroblastoma," <u>European J. Cancer</u> , 31A(2):261-267.	
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	C251	Isenman et al., (1975), "The Structure and Function of Immunoglobulin Domains: II. The Importance of Interchain Disulfide Bonds and the Possible Role of Molecular Flexibility in the Interaction between Immunoglobulin G and Complement," <u>J. Immunology</u> , 114(6):1726-1729.	
	C252	Ko et al., (2004), "Safety, Pharmacokinetics, and Biological Pharmacodynamics of the Immunocytokine EMD 273066 (huKS-IL2)," <u>J. Immunotherapy</u> , 27:232-239.	
	C253	Lo et al., (1992), "Expression and Secretion of an Assembled Tetrameric CH2-deleted Antibody in <i>E. Coli.</i> ," <u>Hum. Antibod. Hybridomas</u> , 3:123-128.	
EXAMINER		DATE CONSIDERED	



FORM PTO - 1449 THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT		ATTORNEY DOCKET NO.: LEX-011 APPLICANT(S): Gillies <i>et al.</i> SERIAL NO.: 09/780,668 EXAMINER: David A. Saunders FILING DATE: February 9, 2001 GROUP: 1644
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C254	Maecker et al., (1997), "DNA Vaccination with Cytokine Fusion Constructs Biases the Immune Response to Ovalbumin," <u>Vaccine</u> , 15(15):1687-1696.
	C255	Mueller et al., (1990), "Enhancement of Antibody-Dependent Cytotoxicity With A Chimeric Anti-GD2 Antibody," <u>J. Immunology</u> , 144(4):1382-1386
	C256	Mueller et al., (1990), "Serum Half-Life and Tumor Localization of a Chimeric Antibody Deleted of the CH2 Domain and Directed Against the Disialoganglioside GD2," <u>Proc. Natl. Acad. Sci. USA.</u> , 87:5702-5705.
	C257	Naramura et al., (1993), "Therapeutic Potential of Chimeric and Murine Anti-(Epidermal Growth Factor Receptor) Antibodies in a Metastasis Model for Human Melanoma," <u>Cancer Immuno. Immunother.</u> , 37:343-349.
	C258	Pertl et al., (2003), "Immunotherapy with a Posttranscriptionally Modified DNA Vaccine Induces Complete Protection Against Metastatic Neuroblastoma," <u>Blood</u> , 101(2):649-654.
	C259	Reisfeld et al., (1994), "Potential of Genetically Engineered Anti-Ganglioside GD2 Antibodies for Cancer Immunotherapy," <u>Prog. Brain Res.</u> , 101:201-212
	C260	Saleh et al., (1992), "Phase I Trial of the Chimeric Anti-GD2 Monoclonal Antibody ch14.18 in Patients With Malignant Melanoma," <u>Hum. Antiob. Hybridomas</u> , 3:19-24.
	C261	Sallusto et al., (1994), "Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells Is Maintained by Granulocyte/Macrophage Colony-stimulating Factor Plus Interleukin 4 and Downregulated by Tumor Necrosis Factor α ," <u>J. Exp. Med.</u> , 179:1109-1118.
	C262	Schlom (1991), "Monoclonal Antibodies: They're More and Less Than You Think," in <u>Molecular Foundations of Oncology</u> , pp. 95-133.
	C263	Weber et al., (2001), "Phase I Trial of huKS-IL2 Immunocytokine in Patients with Prostate Carcinoma: Clinical, PK, and Biological PD Results (Abstract)," <u>American Society of Clinical Oncology Program/Proceedings</u> , 20(Part 1):259a.
	C264	Wen et al., (1994), "Erythropoietin Structure-Function Relationships: Identification of Functionally Important Domains," <u>J. Biological Chemistry</u> , 269(36):22839-22846.
	C265	Gurewich et al., (1988), "Characterization of the Intrinsic Fibrinolytic Properties of Pro-urokinase through a Study of Plasmin-resistant Mutant Forms Produced by Site-specific Mutagenesis of Lysine ¹⁵⁸ ," <u>J. Clin. Invest.</u> , 82:1956-1962.
	C266	Miyake et al., (1988), "Synthesis of Recombinant Human Single-Chain Urokinase-Type Plasminogen Activator Variants Resistant to Plasmin and Thrombin," <u>J. Biochem.</u> , 104:643-647.
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	C267	Nelles et al., (1987), "Characterization of Recombinant Human Single Chain Urokinase-type Plasminogen Activator Mutants Produced by Site-specific Mutagenesis of Lysine ¹⁵⁸ ," <u>The Journal of Biological Chemistry</u> , 262(12):5682-5689.	
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